DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 27 2011

Re: DULERA
Docket No. FDA-2011-E-0142

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,068,832 filed by Schering Corporation, under 35 U.S.C. § 156. The human drug product claimed by the patent is DULERA (mometasone furoate and formoterol fumarate), which was assigned new drug application (NDA) No. 22-518.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that DULERA (mometasone furoate and formoterol fumarate) does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The active ingredients in DULERA (mometasone furoate and formoterol fumarate) have been individually approved previously for commercial marketing or use, in several other approved products including but not limited to the following:

Active Ingredient	Companies	Products	Application Numbers
Mometasone Furoate	Schering	Elocon Topical Cream	NDA 19-625
"	Schering	Asmanex Twisthaler	NDA 21-067
"	Multiple (Altana, G&W Labs, Glenmark Generics, Taro, Tolmar)	Mometasone furoate topical cream	ANDAs[1] 76-171, 77-447, 78-541, 76-679, 76-591
Formoterol Fumarate	Novartis	Foradil Certihaler	NDA 21-592
"	Novartis	Foradil	NDA 20-831
"	Dey Pharma	Perforomist	NDA 22-007

[1] ANDA = abbreviated new drug application.

The NDA was approved on June 22, 2010 , which makes the submission of the patent term extension application on August 19, 2010, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Barry Jacobsen, Esq.
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